



Food and Drug Administration  
OFFICE OF CRIMINAL INVESTIGATIONS  
MEMORANDUM OF INTERVIEW

CASE NUMBER: [REDACTED]

CASE TITLE: THERANOS, INC.

DOCUMENT NUMBER: 280500

PERSON INTERVIEWED: Dr. Edward Szmuc

PLACE OF INTERVIEW: [REDACTED]

DATE OF INTERVIEW: 03/03/2020

TIME OF INTERVIEW: 2:30 PM

INTERVIEWED BY: ASAC George Scavdis

OTHER PERSONS PRESENT: See below.

On March 3, 2020, the case agent interviewed Dr. Edward Szmuc regarding Theranos, Inc. Also present during the interview was AUSA John Bostic, United States Attorney's Office for the Northern District of California, San Jose, California.

Dr. Szmuc resides at [REDACTED] Tempe, Arizona 85284. His cell phone number is [REDACTED] and his email address is [REDACTED]

Between the years of 2013 and 2015, Dr. Szmuc had his own practice in Tempe, Arizona, called Dr. Edward Szmuc, MD. Before he ever referred patients to Theranos for blood testing, he utilized mostly Sonora Quest and LabCorp. for his blood testing services. He probably first heard about Theranos from a drug sales representative; he doesn't recall the name of the representative, nor can he recall the date of that first conversation. Dr. Szmuc does recall that the representative came to his office to pitch Theranos's services. He doesn't recall if the representative left behind any marketing materials. The sales representative probably gave Dr. Szmuc an overview about how Theranos could do laboratory tests using fingerstick draws. The representative told Dr. Szmuc that Theranos was partnered with Walgreens to be in their stores, that they could provide results overnight, and that they sent the samples to California to be tested in their laboratory there. Dr. Szmuc doesn't think Theranos offered esoteric tests. He can't recall seeing news coverage or advertising regarding Theranos.

Dr. Szmuc was told by Theranos that they had quality control and that their tests would be accurate. The accuracy of their test was "absolutely" important to him. He had more than one conversation with the Theranos sales representative. His goal was to use Theranos for all of his patient testing. At the time the Theranos representative pitched him, he was happy with Sonora Quest but he had a previous working relationship with the representative. Dr. Szmuc thought that fingerstick draws were a good idea because patients don't like getting stuck with needles. He took it for granted that Theranos's tests would be accurate and tested. AUSA Bostic asked Dr. Szmuc if he recalled being told by the Theranos sales representative that their tests were accurate, and he responded, "For sure." He remembers that Theranos had "big-time" investors. He can't recall any representations made to him by Theranos that their technology or tests were FDA approved.

AUSA Bostic asked Dr. Szmuc what were the other factors that caused him to use Theranos. He responded that the fingerstick blood draw was a big thing, especially with young females who get a lot of bloodwork done

during their pregnancies. Theranos's association with Walgreens gave him more confidence in Theranos. Based on his conversation with the Theranos sales representative, he started referring patients to them for blood testing. At first, Dr. Szmuc would mostly send a few patients to Theranos for "not important" laboratory tests to see what came back. He most likely asked his patients if they'd like to go to a lab for fingerstick testing, and they 100% would have said, "Yes." As he got more comfortable, he would refer more patients. At some point, most of his patients were going to Theranos.

In terms of volume, he estimates that he saw 30 to 40 patients a day, and probably sent 10 to 15 of them to Theranos for laboratory tests. His practice was to tell his M.A. what labs to order for a patient and the M.A. would do the rest. Patients would go to Theranos with a laboratory slip and have their blood drawn. He didn't do any blood draws in his office. He didn't have any patients who complained about blood draws they received from Theranos. His office had nothing to do with billing for the Theranos blood tests—that was between the patient and Theranos.

Quantitative HCGs are labs done to either identify an early pregnancy or identify an ectopic pregnancy, which are life threatening pregnancies. The HCG values he'd expect to see in a normal pregnancy at first is between 2-1,000. A normal pregnancy doubles every 48 to 72 hours. The HCG value in an ectopic pregnancy may rise just a little bit or stay the same. In reference to HCG tests, Dr. Szmuc said "We rely on those tests immensely." Dr. Szmuc received HCG results back from Theranos that he doubted. He probably called the sales representative with his concerns about the HCG quantitative values he was seeing. Theranos's responses back to him did not allay his concerns. With a test like HCG, a physician must have full confidence, and even one weird result would blow that.

The only problem that Dr. Szmuc ever had with Sonra Quest would be them losing a laboratory sample. He never had a question regarding their results, and he had been using them for almost 30 years. HCG is the most important lab work that an OBGYN does. The results could reveal a life-threatening condition. The results affect the guidance a physician provides to a patient. Normally, Dr. Szmuc would order a 3rd HCG test if he suspected an ectopic pregnancy or miscarriage. He would typically follow the test result down to a negative. But, if HCGs stayed level, it could indicate an ectopic pregnancy that required either a surgical or a pharmaceutical intervention.

Regarding Theranos's CBC test results, Dr. Szmuc had nothing to compare them too, unlike with HCG quantitative values; therefore, he can't speak to the accuracy of the other tests. He explained that if a patient has an HCG value of 5,000 and a later value of 100,000, then a 2nd test value in between that of 5,000 indicates a problem with the test itself.

Dr. Szmuc wasn't happy with Theranos after the problems he saw with their HCG results. He doesn't recall if he stopped sending no-HCG test patients to Theranos after that, but he did not send any more patients for HCG testing. He doesn't recall any follow-up meetings or in-person meetings with anyone from Theranos other than with his sales representative. When speaking with his Theranos sales representative about issues, he doesn't recall the representative giving any assurances about the accuracy of the test. He doesn't remember any explanation for the concerns he raised other than for the representative to say, "We're looking into it."

Dr. Szmuc is currently retired. He started practicing in 1983. His first two years, he worked for CIGNA. After that, he started his own practice. He later joined Southwest Contemporary Women's Care (SCWC) in 2015, which is where Dr. Szmuc worked prior to his retirement. It was an easier schedule and he had friends who worked there. Also, when he had his own practice his wife was his nurse practitioner, but she left to take another job. SCWC has all his patient records, and he has no objection to the case agent asking them to release those records to the Government for review.

Dr. Szmuc said if an HCG value is "below detectable threshold" then it means a negative for pregnancy. If he had a situation where a patient had a positive at home pregnancy test and an HCG blood test that said "below detectable threshold," then that would raise a red flag. If an HCG result comes back as "invalid," then that would be a red flag as well. He doesn't ever remember seeing that result.

SUBMITTED: Electronically submitted by GEORGESCAVDIS

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GEORGE SCAVDIS, ASSISTANT SPECIAL AGENT IN  
CHARGE

DATE: 03/16/2020

APPROVED: Electronically approved by MARKMCCORMACK

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MARK MCCORMACK, SPECIAL AGENT IN CHARGE

DATE: 03/17/2020

DISTRIBUTION: Orig: MWFO  
cc: Prosecution

ATTACHMENTS: None